REMARKS

A final Office Action, Paper No. 14, was issued in this application on December 6, 2002. All pending 4-6, 8, 10-12, 14, 16, 18-22, 24 and 26-28 were rejected. In response thereto, claims 16, 18, 21 and 27 have been amended herein to correct their dependencies. In addition, new claims 30-32 have been added. These claims were originally presented as new claims 15, 17, and 25, respectively, in Applicants' Amendment filed May 29, 2001, but were inadvertently cancelled in Applicants' Amendment filed October 29, 2001 due to Applicants' oversight of the Examiner's renumbering of the claims in Paper No. 6. Accordingly, new claims 30-32 do not constitute the addition of new matter.

In addition, the Specification has been amended and new Figure 4 has been added to bring in language from U.S. Patent No. 4,599,219, to demonstrate the support provided in the specification as filed for the new claim language that "all of said plungers are lifted in unison". Specifically, the language from column 17, lines 24-31, as well as Figure 17 from U.S. Patent No. 4,599,219, have been added to the instant Specification. Since U.S. Patent No. 4,599,219 was incorporated by reference in the Specification as filed (see page 1, lines 32 through page 2, line 4, of the Specification), the amendments to the Specification to not constitute the addition of new matter. MPEP § 2163.07(b). Reconsideration is respectfully requested in light of the following remarks.

A. Rejections under 35 U.S.C. § 112, first paragraph, addressed

Claims 4-6, 8, 10-12, 14, 16, 18-22, 24 and 26-28 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, asserting that the new claim language "wherein all of said plungers are lifted in unison" does not appear to be supported in the original specification. The Examiner states that while "Applicants specifically stated support for these amendments is found on page 3 lines 29-33 of the original specification where USP 4,599,219 ('219 hereafter) . . . MPEP section 608.01(p) teaches mere reference to another patent is not an incorporation of anything therein into the application containing such a reference for the purpose of the disclosure requirement under 35 U.S.C. § 112, 1st paragraph." This rejection is respectfully traversed.

MPEP section 608.01(p) further states that "[a]n application for a patent when filed may incorporate 'essential material' by reference to (1) a U.S. Patent, (2) a U.S. Patent application publication, or (3) a pending U.S. application . . . ". "Essential material" is defined by section 608.01 (p) as "that which is necessary to (1) describe the claimed

invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode".

It is asserted that the present application properly provides a disclosure of the apparatus used in the claimed method, which comprises plungers that are lifted in unison, by specifically incorporating the disclosure of U.S. Patent No. 4,599,219 by reference. The Examiners attention is drawn to page 1, lines 32 through page 2, line 4, of the Specification which states:

> [t]his process and the apparatus for carrying it out are disclosed in detail in U.S. Pats. Nos. 4,599,219 and 5,314,826. Where necessary for a further understanding of the present invention, **the disclosures in these two patents are incorporated by reference herein.** (emphasis added)

Therefore, it is asserted that the Specification as filed fully enables the phrase "wherein all of said plungers are lifted in unison" as recited in independent claims 4 and 8 and therefore claim language meets the requirements of Section 112, first paragraph. With respect to independent claim 22, the rejected claim language is not contained within this claim or its dependents as currently pending. Rather, step (d) of independent claim 22 recites

> (d) repeating the aforementioned steps of dispensing and performing an activated clotting time test on each of said second and third partial samples **by reciprocating the plungers in said second and third cells at the same rate of reciprocation as in said first cell** to obtain a second and third clotting time

However, it is asserted that claim 22 and the claims that depend therefrom are also supported by the incorporation of U.S Patent No. 4,599,219 by reference. Withdrawal of this Section 112, first paragraph, is respectfully requested.

B. Rejections under Obviousness-Type Double Patenting

Claims 4-6, 8, 10-12, 14, 16, 18-22, 24 and 26-28 are rejected under the judicially created doctrine of double patenting as being unpatentable over claims 28-40 of U.S. Patent No. 5,972,712, respectively. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because both teach method of evaluating the clotting characteristics of blood. A Terminal Disclaimer with respect to U.S. Patent No. 5,972,712 will be filed when patentable subject matter has been determined.

C. Rejection under 35 U.S.C. § 103(a)

Claims 4-6, 8, 10-12, 14, 16, 18-22, 24 and 26-28 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,314,826 to Baugh in view of U.S. Patent No. 4,329,302 to Hanahan et al. together further in view of Cooper et al. The Examiner asserts that Baugh teaches a method for the evaluation of clotting characteristics of platelets but is silent to the claimed 1-O-alkyl-2-acetyl-sn-glyceryl-3-phosphorylcholine (AGEPC). The Examiner then asserts that Hanahan teaches that AGEPC is a potent platelet activator, and concludes it would have been within the skill of the art to modify Baugh in view of Hanahan et al. and use AGEPC to gain the advantage of high platelet activation. The Examiner further asserts that Baugh in view of Hanahan is silent to the claim limitation "wherein all of said plungers are lifted in unison," and then asserts that Cooper teaches a similar device for determining coagulation parameters of blood. The Examiner concludes that it would have been within the skill of the art to further modify Baugh in view of Hanahan further in view of Cooper to move all of the plungers in unison to gain the above advantages. This rejection is respectfully traversed.

Independent claims 4, 8 and 25 are distinguished over the cited art by reciting the factor that is varied in order to evaluate the contribution of platelet activation to the activated clotting time test. The variable factor in the present invention is clearly different than that in the Baugh method, as discussed below in detail, and therefore the claimed methods are not obvious in light of the cited references.

Independent claims 4 and 8 are directed to a method for determining platelet functionality of a blood sample using a plunger sensor apparatus comprising two or more test cells and a plunger assembly within each test cell, wherein the method includes the step of performing a clotting test on the aliquot samples by alternately lifting the plunger assembly in each cell and allowing the plunger assembly to descend through the test mixture, wherein all of said plunger assemblies are lifted in unison. Independent claim 22 contains similar language to indicate that all of the plungers are reciprocated at the same rate (see above arguments presented in response to the Section 112, first paragraph rejection). It is believed that such claim limitations clearly distinguish the claimed invention over the cited art for the reasons presented below.

Baugh teaches a method of evaluating platelet functionality which also uses a plunger sensor apparatus; however, the Baugh method comprises two separate phases. The first

phase of the test, termed the "platelet activation phase," activates the platelets by mechanical means, as opposed to chemical means using a platelet activating factor as taught and claimed in the present invention. The platelet activation phase of the Baugh method requires a controlled predetermined activation phase in which a predetermined degree of accountable platelet activation can be obtained and taken into account in determining the activated clotting time (column 5, lines 58-63). Following the platelet activation phase, the ACT test continues though a clotting test phase which follows the usual procedure of the particular ACT test being performed.

More specifically, and with reference to Figures 8A and 8B of the Baugh patent, the method comprises two separate ACT tests 130 and 134, which can be run simultaneously or sequentially (column 11, lines 16- column 12, line 14). The first ACT test (130) has a platelet activation phase (132) with a predetermined **low** intensity of agitation to achieve a relatively higher rate of contribution from platelet activation to the ACT. The second ACT test (134) has a platelet activation phase (136) with a predetermined **higher** intensity of agitation selected to achieve a relatively lower rate of contribution from platelet activation to the ACT. That is, the degree of agitation during the first phase of the Baugh method differs between the two tests (130) and (134). In order to achieve these differing intensities of agitation, the plungers in the respective test cells must be lifted and lowered at different rates (column 11, lines 56-60). This is accomplished either by utilizing one ACT apparatus comprising an assembly apparatus that is designed to reciprocate the plungers independently, or by using two separate ACT apparatuses.

In summary, Baugh teaches a two-phase platelet functionality test comprising a separate platelet activation phase. This separate phase of the test establishes the rate of contribution of platelet activation to the ACT test by mechanically activating the platelets. Thus, the variable in the Baugh method is the rate of agitation in each test (with all other factors held constant). In order to achieve this, the Baugh method requires a means of providing different rates of agitation to each test cell.

In contrast, the method of the present invention is directed to a method of determining platelet functionality or clotting characteristics of a blood sample wherein the contribution of platelet activation to the ACT test is established by chemically activating the platelets. That is, platelets are activated by adding varying amounts of a platelet activating factor to each test cell. Thus, the variable in the present invention is the amount of platelet activating factor that is added to each test cell, with all other factors, including the rate of plunger reciprocation,

held constant. This required feature of the claimed method further supports the claim amendments presented herein. That is, if the amount of platelet activating factor in each test cell is varied, then clearly all other factors in the method of this invention (including the rate of reciprocation of the plungers) must be held constant in order to obtain a titration curve as described on page 8 of the specification.

Further, it is asserted if the Baugh method was modified by adding the platelet activating factor as taught by Hanahan, one would not be able to determine the contribution of platelet activation to the ACT test, since the method would then contain two variables that affect platelet activation, namely, the different rates of agitation and the different amounts of the platelet activating factor. Accordingly, such a modification would render the Baugh method inoperative. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 R.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Further, there is no motivation to modify the method of Baugh by adding a platelet activating factor, since the Baugh method already includes a means for activating platelets.

In addition, it is asserted modification of the Baugh method with the Cooper apparatus would also render the Baugh method inoperable. That is, the plungers in the Cooper apparatus reciprocate at the same rate, whereas the Baugh method requires that the plungers be reciprocated at different rates. Therefore, there can be no teaching or even a suggestion in Baugh or Cooper to modify the Baugh method by using the Cooper apparatus.

Accordingly, it is asserted that it would not have been obvious to modify the teaching of Baugh with the teaching of Hanahan and/or Cooper to arrive at the method of the present invention. Hence, claims 4-6, 8, 10-12, 14, 16, 18-22, 24 and 26-28 are allowable over the combination of Baugh with Hanahan and Cooper. Withdrawal of the Section 103(a) rejection is respectfully requested.

CONCLUSIONS

It is believed that all the claims now pending in this patent application, as amended and described above, are now allowable, which action is respectfully requested. The fee required for the filing of a Petition for a One Month Extension of Time accompanies this response. Should any additional fees be required, please charge Deposit Account No. 50-1123. The Examiner is asked to kindly contact the undersigned by telephone should any outstanding issues remain.

Respectfully submitted,

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Dated

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